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IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF NEW JERSEY

In re:) Chapter 11
)
LTL MANAGEMENT LLC,) Case: 23-12825-MBK
)
Debtor.) Hearing Date: June 12, 2023

MRHFM'S PLAINTIFFS' MOTION TO PRECLUDE CONSIDERATION OF NON-OVARIAN "GYNECOLOGICAL CANCERS" IN ANY PLAN OF REORGANIZATION AND PROPOSED TRUST

LTL Management's second bad faith bankruptcy is premised on Johnson & Johnson's conspiratorial fabrication of a huge new class of alleged "claimants." The Company—in its attack on talc victims and ongoing efforts to "overcome the tort system"—is collaborating with complicit lawyers and law firms¹ to manufacture votes in support of the Debtor's objectively unconstitutional plan of reorganization. This they

¹ The lawyers and law firms collaborating with and assisting Johnson & Johnson in its efforts to trample on individual Constitutional rights and illegally cap the state law remedies available to all plaintiffs identify themselves as the Ad Hoc Committee of Supporting Counsel ("AHCSC").

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cannot do.

MRHFM² moves this Court to Preclude Consideration of these Non-Ovarian "Gynecological Cancers" in this matter because justice so requires. Johnson & Johnson's greed fueled and newfound embrace of a massive class of alleged claimants within this amorphously defined category of women is wholly improper and must be prohibited. *See* Exhibit A to Term Sheet, pgs. A-1 to A-2 (Exhibit 4 admitted during the preliminary injunction hearing on April 18th).³

MRHFM wants to be crystal clear. All women suffering from any cancer deserve and have our empathy, our sympathy, and our support. MRHFM's entire practice is dedicated to representing individuals and families suffering with cancer. MRHFM does not in any way suggest that any of the women listed as claimants by the collaborating lawyers were complicit in the scheme the Debtor, J&J, the AHCSC, and probably FCR Randi Ellis, have concocted and are trying to force on all other victims.

To the contrary, MRHFM condemns this scheme, which attempts to capitalize on these women's struggles and disease in a naked money-grab by a half-trillion-dollar *non*-debtor and lawyers comprising the AHCSC.

² Maune Raichle Hartley French & Mudd LLC ("MRHFM") only represents mesothelioma victims, including seventy-nine plaintiffs with filed cases against Johnson & Johnson.

³ The Debtor wrongly contends that Exhibit A is confidential. This is being challenged by the TCC. *See* Motion to De-Designate Exhibit A, Dkt. 440.

I. JURISDICTION AND VENUE

This Court has jurisdiction to decide this Motion pursuant to 28 U.S.C. §§ 157 and 1334. Venue is proper pursuant to 28 U.S.C. § 1409. Under mandate from the Third Circuit, this Court must close bankruptcy's "safe harbor" to LTL because it has not filed in "good faith." *LTL Mgmt. LLC*, 64 F.4th 88, 93 (3d Cir. 2023).

The Court should promptly decide the many challenges to its subject matter jurisdiction pending in the form of several motions to dismiss. In the meantime, this Court must not permit victims of cancers *without* any scientific or legally supported connection to talc to vote for any plan of reorganization or be paid by a trust.

II. THE MDL PROCEEDINGS IN ARTICLE III DISTRICT COURT

Johnson & Johnson sought and obtained a multidistrict litigation to address ovarian cancer claims against the Company. Years of litigation in the MDL established the link between asbestos contaminated talc and specific forms of ovarian cancer, *not* the panoply of diseases the Debtor purports to compensate as provided for in Exhibit A to its Term Sheet.

A. MDL 2738 Established a Link Between Talc and Ovarian Cancer.

While the J&J talc litigation resided in the United States District Court for the District of New Jersey in MDL 2738,⁴ there was extensive litigation before this Article III

⁴ In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Litigation, MDL 2738.

Court—which, unlike this Bankruptcy Court, has power to decide these issues—of the scientific basis for linking asbestos-contaminated talc exposure to ovarian cancer. *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 184 (D.N.J. 2020) ("The Court finds the weighing of this factor by Plaintiffs' experts to be reliable. There is no dispute that asbestos is carcinogenic and that asbestos has been shown to cause cancer. In that connection, it is not unreliable for the experts to opine that because asbestos has been found in talc, it can similarly cause ovarian cancer.").

After extensive briefing, years of litigation, and a lengthy evidentiary hearing, the MDL court determined that there was a sufficient scientific basis for allowing epithelial ovarian cancer cases to proceed to trial against J&J. In a comprehensive opinion, Judge Wolfson found that plaintiffs' expert, Dr. William Longo, 5 satisfied *Daubert* in testing for the presence of asbestos in J&J's talc,6 as did the plaintiffs' experts on general causation (the ability of talc to cause ovarian cancer). *Id.*, at 147–48, 187.7 Counsel Michelle Parfitt,

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⁵ "Having considered the parties' arguments and Dr. Longo's *Daubert* hearing testimony, I find that Plaintiffs' have met their burden of demonstrating that the doctor's testimony regarding the results of his TEM analysis is reliable for the purposes of admission under *Daubert*."

⁶ "Indeed, the issue of whether there is asbestos, and the amount of asbestos, in Defendants' talc products are key issues in this litigation. For example, Plaintiffs' epidemiology experts rely upon Dr. Longo's report for the assumption that Defendants' talc products contain asbestos to support their opinions that talc use is associated with ovarian cancer. In that connection, to the extent that other Plaintiffs' experts in this litigation rely upon Dr. Longo's findings, their reliance will be limited solely to his finding that Defendants' talc products contain asbestos, and they cannot rely on his opinion that talc users were exposed to asbestos." *Id.*, at 157 (internal citations omitted).

⁷ Three experts offered testimony at the Daubert hearing regarding the connection between talc and ovarian cancer: Dr. Anne McTiernan, an epidemiologist; Dr. Daniel Clarke-Pearson, a gynecologic-oncologist; and Dr. Arch Carson, a toxicologist (the "general causation experts"). *Id.*, at 157. These three experts provided

Co-lead Counsel of the MDL for the plaintiffs, referenced the fact that epithelial ovarian cancer was the focus of the MDL during argument before this Court on April 18th.⁸

B. MDL 2738 Did Not Involve and Did Not Establish A Link Between Many of the Cancers the Debtor Purports to Include in Exhibit A to its Term Sheet.

In opposing Johnson & Johnson's *Daubert* challenges in the MDL, the Plaintiffs Steering Committee stated as follows:

In the broadest sense, there has been no suggestion that there is a causal association between Talcum Powder Products and any other organ or tissue that it comes in contact with, including...anal cancers. Nor has it been suggested that perineal Talcum Powder exposure is associated with other *gynecologic* cancers like cervical or uterine cancer. Indeed, with respect to the "specificity" aspect of Hill, it has been noted that "perineal talc exposure is specifically associated with cancer of the ovary and no other organs."

Ex. 1, Plaintiffs' Steering Comm.'s Omnibus Mem. of Law in Resp. to J&J's Mot. to Exclude, 5/31/19, pgs. 179-80 (emphasis original). Neither J&J nor the plaintiffs litigating in the MDL contended that all "non-ovarian gynecological cancers"—now compensable in the Term Sheet—were connected to talc. Johnson & Johnson argued as follows:

- "Plaintiffs have separately attempted to show that talc use causes high-grade serous ovarian cancer ("HGSOC") – one of many diverse subtypes of ovarian cancer – through a flawed "systematic metaanalytic review" conducted by Dr. Smith-Bindman." Pg. 6.
- "If talc were carcinogenic, it would likely cause vaginal, cervical and endometrial cancer...but it does not, as plaintiffs' experts concede."

exemplar testimony at the hearing for Plaintiff expert epidemiologists and gynecologic oncologists disclosed in the MDL.

⁸ Judge Wolfson found "certain epithelial ovarian cancers could be caused by and were caused by exposure to talcum powder. Not uterine cancer, not vaginal cancer, not cervical cancer, not categorically gynecological cancers, but ovarian cancers." <u>Ex</u>. 2, Tr. 4/18/23, pg. 334.

Pg. 88.

- "The different subtypes also arise from different tissues—for example HGSOC, largely arises from the fallopian tubes, while endometrioid and clear cell carcinoma develop in the uterine endometrium—and they develop as a result of different sets of genetic mutations. Unsurprisingly, then, the different subtypes of ovarian cancer all have different risk factors, and it is unlikely that one substance could cause all (or even most) of them." Pg. 83.
- "[I]n March of this year, a review article in the New England Journal of Medicine identified risk factors for mucinous and serous ovarian cancer and *did not list talc.*" Pg. 110 (emphasis original).

See Ex. 3, J&J Mem. of Law in Supp. of Mot. to Exclude Plaintiffs' Experts' General Causation Opinions, 5/7/19 ("J&J MDL Opp.").

If the Debtor and its collaborators seek to compensate victims of non-ovarian "gynecological cancers," evidence must be adduced, tested, and ruled upon by an Article III District Court with power to hear and decide these issues. Until that happens, victims of these cancers must not be allowed to vote for or against any plan of reorganization in this destined-for-dismissal second bad faith bankruptcy.

III. LTL MANAGEMENT CANNOT INCLUDE CANCERS WITHOUT LEGAL AND SCIENTIFIC LINKS TO TALC IN ANY PLAN OR TRUST

Absent LTL's second bad faith bankruptcy filing, *none* of the tens of thousands of non-ovarian "gynecological cancers" had a compensable claim in MDL 2738. There, Johnson & Johnson argued against several types of cancer that are now allegedly claimants in Exhibit A to its Term Sheet. These claims are not compensable in a trust.

A. The Debtor's Plan in LTL2 includes Cancers with No Connection to Talc.

Johnson & Johnson, now desperate to buy votes and to fabricate the appearance of support for its second abusive petition, has attempted to vastly expand the universe of claimants. It is no surprise that the AHCSC, allegedly representing this vast new class of claimants, is confident their clients will support *any plan* that provides *any compensation* to these unfortunate women. The AHCSC knows these claims are worthless outside bankruptcy and outside its collusive ballot-box-stuffing scheme with the Debtor and J&J.

The Debtor purports to treat as "Quickpay" claims for mucinous, stromal, germ cell, borderline tumors, and non-ovarian gynecological cancers. *See* Exhibit A. Each of these were largely ignored in the MDL because the plaintiffs never alleged such a connection. There is zero evidence before this Court that exposure to talcum powder products has been causally linked to increasing the risk of, or causing, these types of cancers, let alone sufficient evidence to meet *Daubert* and its progeny. Yet, the Debtor purports to allow claimants allegedly diagnosed with these types of cancers to vote on its "plan."

Who benefits from this type of trust? J&J and the AHCSC members that stand to make hundreds of millions of dollars in fees for claims that were not litigated in state or federal trial courts, were not viable in the tort system, and for which the AHCSC has produced zero evidence of general causation. None of the AHCSC's collaborating lawyers was litigating non-ovarian "gynecological cancers" in state courts prior to LTL's first bad

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faith bankruptcy filed in October 2021 (or since). This flagrant, pre-textual manufacture of a gigantic class of new potential claimants was done for one purpose only: to manufacture votes.

B. <u>"All Talc Claims" in LTL1 Did Not Include the Claims the Debtor Now</u> Wants to Include in LTL2.

Prior to the Third Circuit decision in *LTL1*, the Debtor said it was critical for there to be an evidentiary basis to "assess the validity of these claims." Ex. 4, Tr. 7/26/22, pgs. 101-02. LTL viewed the distinctions between cancer types to be critical and sought "an aggregate estimation of <u>all talc claims</u>." *LTL1*, Debtor's Mem. Need for Estimation, ¶ 58 (Dkt. 2726) (emphasis).

The Debtor said "[t]here are many subtypes of ovarian cancer and mesothelioma across claims already pending against the Debtor . . . The different subtypes of ovarian cancer develop in different types of cells, look different under a microscope, and involve mutations of different genes, and have different risk factors and causes . . . " *Id.*, at ¶ 46. Since "the strength of any theoretical correlation between use of Johnson's Baby Powder can vary considerably by disease subtype," any compensation "paid on individual claims should depend, in part, on disease subtype and severity of disease." *Id.*, at ¶ 47. When advocating for the Two Step signature estimation boondoggle in *LTL1*, the Debtor said the Court should appoint two experts: one to opine on economic issues and another on "medical/science issues." *Id.*, at ¶ 2.

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Notably absent from the Debtor's request for Estimation of "all talc claims" in *LTL1* is any mention of mucinous, stromal, germ cell, borderline tumors, and non-ovarian "gynecological cancers." There was no indication that LTL intended to compensate victims of these diseases during over 18 months of litigation in the first bankruptcy proceeding. In *LTL1*, the Debtor demanded the Court consider the scientific evidence of any connection between talc and specific diseases. In *LTL2*, it's all about the vote.

Only after losing before the Third Circuit did the Debtor—with the help of collaborating lawyers and probably the FCR—broaden the universe of diseases at issue. Now, desperate to find support for its bogus plan, LTL seeks to include this wide variety of cancers—claims that have *zero* value in the tort system—and expects the collaborating lawyers to tip the scales for it in a vote.

C. Claims Worth Nothing in the Tort System are Worth Nothing in a Trust.

"Creditors" who don't have viable claims outside of bankruptcy do not suddenly become real creditors inside bankruptcy. There is no evidence before this Court that any of these non-ovarian "gynecological cancers" was viable in or had any value in the tort system. Indeed, the Debtor's and J&J's newfound love for this vast new class of cases and its agreement to include them as claimants—notwithstanding the fact that they would be subject to summary judgment in the MDL—is yet another fundamental violation of the

⁹ The Debtor noted the plaintiffs in the MDL were *not* alleging that talc was a cause of "mucinous ovarian cancer." *Id.*, ¶ 47 n.24.

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Debtor's fiduciary duty to maximize and preserve the assets of the Estate for the benefit of real creditors.

Simply put, the Debtor purports to pay "claimants"—who are owed nothing *outside* this bad faith bankruptcy—to buy their votes *inside* this bad faith bankruptcy. These non-ovarian "gynecological cancers" must be excluded from any vote or plan. If and only if (1) there is an evidentiary showing of sufficient scientific basis to (2) demonstrate a causal link between these cancers and talc that (3) would pass *Daubert* analysis as (4) determined by an Article III court, likely MDL 2738, can these cancers be considered in this case.

That evaluation would, of course, take years or more. It does not appear that any of the collaborating AHCSC were litigating non-ovarian "gynecological cancers" in the tort system (including in MDL 2738) prior to the Debtor and J&J instituting its first badfaith bankruptcy. Indeed, the "leader" of the AHCSC, Mikal Watts, has not litigated or even filed a single talc lawsuit (ovarian cancer or "gynecological cancer" or mesothelioma) in the tort system.

The AHCSC, the Debtor and J&J have not provided any evidence to support a causal link between these non-ovarian "gynecological cancers" and talc to this Court. This is wrong. The Debtor's ballot-box-stuffing sleight-of-hand with the AHCSC is wrong. This Court must not permit it.

Respectfully submitted:

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EXHIBIT 1

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION Civil Action No. 3:16-md-2738-FLW-LHG

MDL No. 2738

THIS DOCUMENT RELATES TO ALL CASES

THE PLAINTIFFS' STEERING COMMITTEE'S OMNIBUS MEMORANDUM OF LAW IN RESPONSE AND OPPOSITION TO DEFENDANTS' JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MOTION TO EXCLUDE PLAINTIFFS' GENERAL CAUSATION OPINIONS

[CORRECTED VERSION OF ECF DOC. 9888]

literature. 465 The PSC's experts reasonably relied the evidence discussed above to support their conclusion regarding biological plausibility. Any weaknesses in their opinions or evidence should be resolved by a jury.

G. THE PSC'S CAUSATION EXPERTS MAY RELIABLY OPINE THAT THE "SPECIFICITY" ASPECT OF THE BRADFORD HILL CAUSATION GUIDELINES ARE SATISFIED WHERE THERE IS EVIDENCE OF SPECIFICITY BETWEEN TALCUM POWDER PRODUCTS AND OVARIAN CANCER GENERALLY AND IN EPITHELIAL OVARIAN CELLS SPECIFICALLY

Another factor to be considered in a Bradford Hill analysis is the "specificity" of the proposed relationship. If a proposed causal association is shown to have a single effect, as opposed to multiple effects, the more likely the proposed causal association. 466 Indeed, where there are multiple carcinogens in Talc, as there are multiple carcinogens in cigarettes, specificity may be even less relevant. 467 For these

Cigarette manufacturers have long claimed that because cigarettes have been linked to lung cancer, emphysema, bladder cancer, heart disease, pancreatic cancer, and other conditions, there is no specificity and the relationships are not causal. There is, however, at least one good reason why inferences about the health consequences of tobacco do not require specificity: Because tobacco and cigarette smoke are not in fact single agents but consist of numerous harmful agents, smoking represents exposure to multiple agents, with multiple possible effects. Thus, whereas evidence of specificity may strengthen the case for

⁴⁶⁵ See generally PSC's Memorandum of Law in Response and Opposition to J&J's Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions.

⁴⁶⁶ See Hill (1965) at 297; Rothman, Modern Epidemiology at 27-27.

⁴⁶⁷ The *Reference Manual* notes the following:

reasons, the original criterion of specificity is "widely considered weak or irrelevant from an epidemiologic standpoint." 468

J&J argues that the association here is highly "unspecific" and that PSC's experts wholly disregarded it.⁴⁶⁹ J&J is wrong on both accounts there is evidence of specificity and the PSC's experts address it.⁴⁷⁰

1. There is Evidence that Perineal Talcum Powder Exposure is Specifically Correlated Only to Ovarian Cancer and, more Particularly, to Epithelial Ovarian Cancer

In the broadest sense, there has been no suggestion that there is a causal association between Talcum Powder Products and any other organ or tissue that it comes in contact with, including perineal of anal cancers. Nor has it been suggested that perineal Talcum Powder exposure is associated with other *gynecologic* cancers,

causation, lack of specificity does not necessarily undermine it where there is a good biological explanation for its absence." *Ref. Man.* at 606.

⁴⁶⁸ K.M. Fedak, *et al.*, *Applying the Bradford Hill criteria in the 21st Century: How Data Integration Has Changed Causal Inference In Molecular Epidemiology*. 12 Emerging Themes in Epidemiology 14 (2015), attached as **Exhibit 161**. For instance, smoking is generally accepted to be a cause of lung cancer, yet smoking is also associated with COPD, heart disease, stroke, and asthma, amongst other diseases. Asbestos, is generally accepted to cause mesothelioma, lung cancer, and ovarian cancer. Asbestos is also generally accepted to cause asbestosis/pulmonary fibrosis, pleural inflammation and thickening.

⁴⁶⁹ Defs.' Mem. at 82 and n. 191.

⁴⁷⁰ Kane Rep. at 34; McTiernan Rep. at 65; Moorman Rep. at 37; Siemiatycki Rep. at 66; Singh Rep. at 64; Smith-Bindman Rep. at 39; Carson Rep. at 9; Clarke-Pearson Rep. at 8; Smith Rep. at 20; Wolf Rep. at 15.

like cervical or uterine cancer. Indeed, with respect to the "specificity" aspect of Bradford Hill, it has been noted that "perineal talc exposure is specifically associated with cancer of the ovary and no other organs."⁴⁷¹

There is evidence that the specificity of the Talcum Powder ovarian cancer relationship is even *more* specific than to ovarian cancer generally. The epidemiologic evidence has noted that the association is most closely correlated with cancer of the ovarian *epithelium* (epithelial ovarian cancer) and not to other ovarian cancer like germ cell of stromal cell ovarian cancer. The *epithelial* ovarian cancer data is summarized in *Section III(A)(1)(d)*, *supra*, in relation to the meta-analyses, case control and cohort studies.

Even more specific than that, studies of serous cancer, an epithelial cancer, shows a risk. This includes Gertig (2000), a cohort study (which J&J touts as the highest "level" of observational evidence). That statistically significant data is below:

SEROUS OVARIAN CANCER

Study Type	Year	Author	OR	95%CI
Meta-analysis	2018	Taher	1.38	1.22-1.56
Meta-analysis	2018	Penninkilampi	1.32	1.22-1.43
Meta-analysis	2018	Berge	1.24	1.15-1.34
Case Control	2016	Schildkraut	1.38	1.03-1.85
Case Control	2016	Cramer	1.42	1.19-1.69
Case Control	2009	Wu	1.70	1.27-2.28

⁴⁷¹ Health Canada Assessment at 20 (citing Taher, et al. (2018)).

EXHIBIT 2

IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: . Case No. 23-12825 (MBK)

LTL MANAGEMENT LLC,

. U.S. Courthouse

Debtor. . 402 East State Street

Trenton, NJ 08608

.

LTL MANAGEMENT LLC, . Adv. No. 23-01092 (MBK)

Plaintiff,

THOSE PARTIES LISTED ON APPENDIX A TO COMPLAINT AND JOHN AND JANE DOES 1-1000,

v.

Defendants. . Tuesday, April 18, 2023

..... 10:00 a.m.

TRANSCRIPT OF HEARING ON

MEMORANDUM OF LAW IN SUPPORT OF MOTION BY MOVANT ANTHONY HERNANDEZ VALADEZ FOR AN ORDER (I) GRANTING RELIEF FROM THE AUTOMATIC STAY, SECOND AMENDED EX PARTY TEMPORARY RESTRAINING ORDER, AND ANTICIPATED PRELIMINARY INJUNCTION, AND (II) WAIVING THE FOURTEEN-DAY STAY UNDER FEDERAL RULE OF BANKRUPTCY PROCEDURE 4001(a)(3) [DOCKET 71]; AND DEBTOR'S MOTION FOR AN ORDER (I) DECLARING THAT THE AUTOMATIC STAY APPLIES OR EXTENDS TO CERTAIN ACTIONS AGAINST NON DEBTORS OR (II) PRELIMINARILY ENJOINING SUCH ACTIONS AND (III) GRANTING A TEMPORARY RESTRAINING ORDER EX PARTE PENDING A HEARING ON A PRELIMINARY INJUNCTION [ADVERSARY DOCKET 2]; AND MOTION TO SEAL; AND SERVICE PROCEDURES MOTION

BEFORE THE HONORABLE MICHAEL B. KAPLAN UNITED STATES BANKRUPTCY COURT JUDGE

Audio Operator:

Kiya Martin

Proceedings recorded by electronic sound recording, transcript produced by transcription service.

J&J COURT TRANSCRIBERS, INC. 268 Evergreen Avenue Hamilton, New Jersey 08619 E-mail: jjcourt@jjcourt.com

(609) 586-2311 Fax No. (609) 587-3599

was not. That's why they dismissed.

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In Your Honor's words, in Your Honor's words at the first day hearing, the world is watching. We have every confidence that Your Honor will do the right thing. Thank you, 5 Your Honor.

> Thank you, counsel. THE COURT:

MS. PARFITT: Your Honor, good evening and thank you for the opportunity to speak. Your Honor, I haven't had a chance to be before you up until now, but my name is Michelle 10 Parfitt and I co-lead the multi district litigation along with Leigh O'Dell.

I've listened today and I've listened for the last 18 13 months and I do have a few remarks. And if you will indulge 14 me. And I'm trying to be very conscientious of the needs of my 15 other colleagues.

Your Honor, when I heard Ms. Brown say that the tort system is broken, it has failed, the tort system has not 18 failed. It has been a system of justice that has been embraced 19 by both sides of the table. It has been a system of justice that has worked for centuries. It is a system of justice that provides choices, rights, and liberties. One has to ask why, why does LTL seek to retreat to the bankruptcy system?

They have a system of justice that they have embraced, but here today in this case they retreat to the bankruptcy system. To say it's perverse, is perverse the fact

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that the Honorable Judge Wolfson for the last seven years $2 \parallel$ governed the multi-district litigation and put attorneys to task to prove the case, to prove the science before we were able to embark on a liability of the case we were to prove the 5 science of the case. Not a check box on a bankruptcy form, but to prove what diseases are related to what exposures.

And Judge Wolfson, after a very lengthy Daubert 8 proceeding, and after years of preparing for that determined that there were certain cancers, certain epithelial ovarian 10 cancers that could be caused by and were caused by exposure to talcum powder. Not uterine cancer, not vaginal cancer, not cervical cancer, not categorically gynecological cancers, but 13 ovarian cancers.

What they seek to do is to come into the bankruptcy court, keep our clients there, provide them with a checklist of broad ranges of mesothelioma, asbestos exposure, broad ranges of gynecological cancers. You asked Mr. Birchfield why the increase of cases? You know why there's an increase of cases, 19 \parallel Your Honor, at 60, 70,000? Ask what kinds of cancers are those? Is it a grab bag or are they cancers that are proved by the science? Perverse, the word perverse is used. What's perverse is for a half trillion dollar corporation to retreat to the bankruptcy system claiming the need for refuge and protection for their company.

Dishonestly, that was used too. Dishonest people,

dishonest claimants. What's dishonest is to sell and 2 manufacture to consumers around the world a product that contained asbestos and they knew was not safe for 100 more years. That's dishonest.

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Time. Your Honor, our claimants don't have time. J&J has all the time in the world. They can spend five years working through the different formulas and time lines for a bankruptcy system. Our clients have spoken. We are their voices. They have said give us at least the right, the choice to go into a tort system. At least give us the right to speak. Don't force us into a system we never asked to be in. those that choose, that's a good right, that is their choice. 13 \parallel For those that believe the tort system can be fair.

If J&J believes what they say, that they want to give our claimants fair and reasonable compensation, you can do that in a tort system. You can do it in a trial, outside of a trial, in a resolution or not. You don't need to cram the people into a bankruptcy system under a false premise that you are insolvent or that you have financial distress.

THE COURT: All right, counsel.

MS. PARFITT: Thank you.

THE COURT: Thank you.

MS. JOHNSON: Good evening, Your Honor. Ericka Johnson from Womble Bond Dickinson on behalf of the Ad Hoc Committee of State Attorney Generals. I rise just to raise a

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON)	
TALCUM POWDER PRODUCTS)	
MARKETING, SALES PRACTICES AND))	MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION)	
	_)	
)	
This Document Relates To All Cases)	
	_)	

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE PLAINTIFFS' EXPERTS' GENERAL CAUSATION OPINIONS

DRINKER BIDDLE & REATH LLP

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SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP 1440 New York Avenue, N.W. Washington, D.C. 20005 (202) 371-7000

Attorneys for Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.

response have been all over the map – finding "(1) random or 'sine wave' (up and down) risk; (2) convex (up then down) risk; (3) concave (down then up) risk; and (4) even decreasing risk" – a random pattern of results that "is a red flag to epidemiologists" evaluating study data. ¹² "Moreover, study authors and plaintiffs' experts all agree that there are major challenges to interpreting the study findings on dose-response because there can be no assurance that any estimates of talc use are accurate or valid," since there is no way to measure how much talc a woman uses (let alone, how much – if any – actually enters the body). ¹³

• The remaining Bradford Hill factors do not support causation. There is no plausible biological mechanism of injury (as discussed in more detail in defendants' separate memorandum addressing biological plausibility); plaintiffs' experts' theory is not supported by experimental evidence; and it is incoherent with broader scientific knowledge, including the knowledge that genetic mutations are the established cause of cancer and that talc does not cause mutations. Plaintiffs' experts' opinions also fail to grapple with the improbability that talc exposure causes all (or even most) of the various different subtypes of ovarian cancer, which are essentially different diseases with different suspected etiologies.

Second, plaintiffs have separately attempted to show that talc use causes high-grade serous ovarian cancer ("HGSOC") – one of many diverse subtypes of ovarian cancer – through a flawed "systematic meta-analytic review" conducted by Dr. Smith-Bindman. But Dr. Smith-Bindman's analysis is methodologically flawed and patently unreliable. Dr. Smith-Bindman reviewed the larger body of literature first and then analyzed particular subsets of data from prior cherry-picked

⁽Expert Report of Christian Merlo, M.D., M.P.H. ("Merlo Rep.") at 32, Feb. 25, 2019 (attached as Ex. C13 to Tersigni Cert.).)

⁽Expert Report of Gregory Diette, M.D., M.H.S. ("Diette Rep.") at 3, Feb. 25, 2019 (attached as Ex. C18 to Tersigni Cert.).)

shown to be at an increased risk of developing cancer²⁰⁸ – only adds to the incoherence of plaintiffs' experts' opinions.

A final indication of incoherence is the lack of any increased risk of cancer in tissues that are much closer to the perineum than the fallopian tubes and ovaries. If talc were carcinogenic, it would likely cause vaginal, cervical and endometrial cancer, since those tissues are closer to the perineum and thus likely to be first exposed if talc enters the vaginal cavity.²⁰⁹ But it does not, as plaintiffs' experts concede.²¹⁰ This, too, shows that plaintiffs' experts' causation theory is not coherent with existing scientific knowledge.²¹¹

Analogy. Plaintiffs' experts generally opine that the putative causal relationship between talc and ovarian cancer can be analogized to asbestos causing

²⁰⁸ (Neel Rep. at 28.)

⁽See Smith Dep. 347:14-18 (agreeing that if talc migrates to the ovaries, tissues and organs along the genital tract would be exposed to talc).)

⁽See, e.g., Smith Dep. 375:1-24 (testifying that she is not aware of any evidence that genital talc use increases the risk of vulvar, vaginal, uterine or rectal cancer); Carson Dep. 200:9-14 (no studies that show inflammation or oxidative stress as a result of genital talc use in the rectal, vulvar, vaginal, cervical and uterine tissues); Clarke-Pearson Dep. 213:22-25 (same).)

The incoherence of plaintiffs' experts' opinions is further underscored by the fact that anti-inflammatories have not been shown to reduce the risk of ovarian cancer, as discussed more fully in defendants' Biological Plausibility Brief.

that talc use causes every subtype of epithelial ovarian cancer, even though these are effectively different diseases.

As Dr. Smith-Bindman explains, the subtypes of ovarian cancer "vary in their pathological appearance, molecular biology, risk factors, etiology, and prognosis." The different subtypes also arise from different tissues – for example HGSOC, largely arises from the fallopian tubes, while endometrioid and clear cell carcinoma develop in the uterine endometrium – and they develop as a result of different sets of genetic mutations. Unsurprisingly, then, the different subtypes of ovarian cancer all have different risk factors, ¹⁹³ and it is unlikely that one substance could cause all (or even most) of them. ¹⁹⁴ This lack of specificity further highlights the unreliable nature of plaintiffs' experts' opinions. *See Zoloft 1*, 26 F. Supp. 3d at 463 (excluding expert's testimony on causation because, although the expert cited studies demonstrating that "Zoloft [wa]s significantly

⁽Smith-Bindman Rep. at 9.) The remainder of plaintiffs' experts generally gloss over the differences between the ovarian cancer subtypes. As set forth in defendants' Biological Plausibility Brief, those differences have important implications for plaintiffs' experts' biological plausibility theories, and their failure to account for them underscores the unreliability and superficiality of their analyses.

^{193 (}*See* Neel Rep. at 13-14.)

⁽*Cf.*, *e.g.*, Dep. of Michael Crowley, Ph.D. 212:14-213:2, Jan. 4, 2019 (attached as Ex. B37 to Tersigni Cert.) (agreeing that is possible that an agent can cause one type of cancer but not another).)

This is such a case. Numerous public health authorities that have studied the issue have reached the *exact opposite conclusion* as to any connection between talc and ovarian cancer as that espoused by plaintiffs' experts here. The FDA reviewed the relevant body of scientific literature in 2014 and "did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer." Similarly, NCI has repeatedly reiterated its conclusion that the "weight of the evidence does not support an association" between talc use and increased ovarian cancer risk. And IARC concluded that talc is only "possibly carcinogenic" to humans. And IARC concluded that talc is only "possibly carcinogenic" to humans. March of this year, a review article in the New England Journal of Medicine identified risk factors for mucinous and serous ovarian cancer and did not list talc.

²⁵⁸ FDA Denial Letter at 1 (emphasis added).

See, e.g., 2019 NCI PDQ (emphasis added).

IARC 2010 Monograph at 412. IARC classifies talc as a "Group 2B" agent that is "possibly carcinogenic" to humans, which means there is "*limited*" *evidence of carcinogenicity*. This is the same category into which it has placed pickled vegetables, ginkgo biloba, and aloe vera whole leaf extract. *See* IARC 2010 Monograph at 412.

Morice 2019 at 1257 tbl. 1; see also World Cancer Res. Fund Int'l Continuous Update Project, Diet, Nutrition, Physical Activity and Ovarian Cancer (revised 2018) (attached as Ex. A154 to Tersigni Cert.) (review by Dr. McTiernan's panel not listing talc use as a risk factor for ovarian cancer). As explained in Dr. Mossman's report, The New England Journal of Medicine has the (cont'd)

EXHIBIT 4

UNITED STATES BANKRUPTCY COURT DISTRICT OF NEW JERSEY

IN RE: Case No. 21-30589 (MBK)

LTL MANAGEMENT LLC,

.

Debtor.

LTL MANAGEMENT, LLC, . Adversary No. 21-3032 (MBK)

Plaintiff,

Clarkson S. Fisher U.S.

v. Courthouse

THOSE PARTIES LISTED ON . Trenton. N.T 09600

APPENDIX A TO COMPLATIVE

and JOHN AND JANE DOES 1 TO 1000,

Defendants. . Tuesday, July 26, 2022

10:04 a.m.

TRANSCRIPT OF MOTIONS HEARING BEFORE THE HONORABLE MICHAEL B. KAPLAN UNITED STATES BANKRUPTCY COURT JUDGE

APPEARANCES:

For the Debtor: Jones Day

By: GREGORY M. GORDON, ESQ.

DANIEL B. PRIETO, ESQ.

2727 North Harwood Street, Suite 500

Dallas, TX 75201

For the Official Otterbourg P.C.
Committee of Talc By: MELANIE CYGANOWSKI, ESQ.

Claimants 1: 230 Park Avenue New York, NY 10169

Audio Operator: Wendy Quiles

Proceedings recorded by electronic sound recording, transcript produced by transcription service.

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1 anything above zero is overpaying.

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I think if you peel it back, what the debtor is $3 \parallel$ really saying is, is we want you, Judge, to agree that we owe $4\parallel$ nothing and so we would like to do a year-long estimation process so we can convince you of the science and get you to 6∥ say we owe nothing. And they're viewing it as really as a mediation tool. And, you know, echoing Mr. Molton's comments, I don't think that's an appropriate use of estimation and I don't think it's a path to anywhere in this case.

Anyway, thank you, Your Honor. I appreciate the opportunity to participate by Zoom.

THE COURT: Thank you, Mr. Pfister. And I hope you 13 get better --

MR. PFISTER: Thank you.

THE COURT: -- and look forward to seeing you on this coast.

> Anyone else wish to be heard? Don't feel compelled. (Laughter)

THE COURT: All right. Mr. Gordon, did you want to 20 respond?

MR. GORDON: I do, Your Honor. I can be relatively 22 brief I think.

Just starting with a point that Mr. Pfister made and others, there seems to be a number of efforts to try to paint us as changing positions. And I don't think, Your Honor, that

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1 we've changed positions on anything. Mr. Pfister suggests that 2 today, we're now arquing that J&J's consent is required for 3 plan confirmation. I did not make that argument.

The point I was making is that we're in a judicial proceeding. We believe, like the claimants, that we have 6 rights to be heard, that we have due process rights to make our case and it was unimaginable to me that we could have a situation where a plan gets approved based on the claimants agreeing to their own demands or we don't have a full right to be heard in terms of what the results of that settlement with themselves are and without a right to fully defend ourselves. So there's no change in position.

Also Mr. Pfister said that in his view, this case is 14 unique because this company has been telling this Court from the beginning that it owes nothing. And we do believe we owe nothing. If the merits are properly examined with all the facts, we do believe that's the case. I can tell Your Honor that many companies have gone into asbestos cases making the exact same argument. It was made in Garlock. It was made in That was the view in Kaiser Gypsum. Bondex. There, the arguments were different. It was based on the fact that the products at issue had chrysotile asbestos not anthophyl, that the exposures would not -- that that's a less toxic asbestos, that the exposures were not sufficient to cause disease and no liability. So I just want to say there's nothing unique.

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But there's a suggestion embedded in what he said 2 which is a suggestion that we're not even proceeding in good $3 \parallel$ faith in this case, that we're not negotiating in good faith, and I assure Your Honor that the debtor and J&J have taken the mediation very seriously. Significant offers have been made and to imply that maybe there's an unwillingness to make any kind of material offer to resolve this case and move on and be done with it, that's completely incorrect.

As to the U.S. Trustee's comments about the Rule 706 expert, all I would say there is we gave a lot of thought to those issues as well, did research. Knowing Your Honor, I know you did too. And I would say a couple things, and I was remiss probably in not saying something before. The reason we propose two experts is because we can't envision anyone, any single person, who would have the requisite expertise to address both science issues, medical science issues, and economic issues.

We can envision that there are people who have the expertise to advise on all the medical science issues and then on all the economic issues. So I did want to be clear. don't think I said it before. That's the reason we thought that two were necessary. We just racked our brains and we just couldn't think of a single individual or type of individual who would provide the expertise across the spectrum of issues who would have to be considered.

But with respect to the U.S. Trustee's point

1 specifically, she's right that we found as well there's sort of a pure 706 expert, which is more like an expert witness who $3\parallel$ writes reports can be cross-examined. And then the other concept we found was a technical advisor serving more in the role of a technical advisor. And that seemed to us what Your 6 Honor was thinking about here. We don't know exactly what Your Honor was thinking about, but at least I think when we were laying out our proposal, that's the way we were thinking about, somebody who could provide technical, scientific, or economic advice to the Court on issues that, you know, are pretty, you know, are pretty complex and not easy to understand for, you know, someone who's not immersed in those issues day-to-day.

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So we think there is plenty of authority for that. And that would be someone that wouldn't be an expert report, per se, or there wouldn't be cross-examination, per se. admittedly, we've seen two different approaches adopted by courts and we don't see either of them falling in the category of a special master. That's not what we were seeing here. special master to us is where the court's basically delegating responsibility to make a decision or recommend a decision. didn't see it that way. We saw it more in terms of providing needed advice to the Court and assessing the issues that would be presented by the experts in the case.

Mr. Thompson, the one thing -- I mean, obviously, 25∥ he's made very clear and his firm has made very clear, they are

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1 opposed to the bankruptcy period. They're opposed to every $2 \parallel$ bankruptcy. They want to litigate every one of their cases and they argue that every single one of their claimants would $4\parallel$ rather proceed in court than accept a fixed payout under a plan. But at the same time, he has to concede he hasn't seen 6 any plan. He doesn't know what values might be offered. me, I don't think we can put much stock in a position like that where a party's telling you that no agreement would be acceptable. We don't care about the aggregate value. Well, of course, they don't care about the aggregate value. to know what the claim values are.

But he did attempt, and we've seen this multiple 13 times, to distinguish the Paddock case. And he said that company was in distress. That's different. Well, that company's equity was preserved. He also said that there was no PI in that case. That's a totally different case. Well, there was no PI in that case because there was no litigation in that case. All their claims were handled under administrative settlement. So that's just not a fair way to distinguish Paddock. And of course Paddock, although a Texas divisional merger wasn't utilized, the equivalent type transaction was done in that case and there was a funding agreement and that sort of thing.

Ms. Jones, again, in another effort to paint us as changing our position, said that what she heard today was very 1 troubling because that was contrary to our assertion that we $2 \parallel$ were intending to fund claims in full. And she was basically $3 \parallel$ suggesting that because we're not, at this point, supportive of a pay-as-you-go plan that that's a change in position. That's no change in position. All the parties know that. We've been very clear from day one in this case that we want a global permanent resolution of this liability. We want to fund the liability and we want to be done with the liability.

And, obviously, what's being proposed by way of cram down is a plan that wouldn't do that. It basically takes off the table immediately what our objective is in this case. that is not a change in position. The reason we want to focus on the aggregate liability is we want to pay a funding amount that's acceptable to the parties and we want to be done.

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There's no surprise in that. There's no change in position.

There's also been a lot said by, I think Mr. Satterley made a comment, Mr. Molton made a comment, about the PIQ discovery and the trust discovery. And, again, we hear this in every case. I think Mr. Satterley said we don't need the information. We already have the information.

Well, we don't have the information. I put up the statistics from the other cases to show you that those companies didn't have the information either. And it's always been beyond me why there's so much opposition to discovery that's intended just to seek the basic information that any

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1 court would want to assess the validity of these claims. Why is there such opposition to that? Why don't they want to tell $3 \parallel$ us from whom else they're seeking recoveries? Why don't they $4\parallel$ want to tell us what other recoveries they've gotten in the same claims?

On the trust discovery, why don't they want us to know that they're seeking recoveries from other trusts with respect to the same claims? That's all we're asking. to know. These are claims that there's either several liability or joint and several liability. Aren't we entitled to know whether or not they've actually recovered on those claims already or they're asserting somewhere else that they've been exposed to other companies' products.

This was a gigantic battle in the Garlock case and Judge Hodges ultimately said, I think some discovery is permitted. And I know you've read his opinion. At the end of the day, he said, look, I limited your discovery, but I looked at 15 cases and in every single one of the case, it was clearly established that the plaintiffs suppressed evidence of having submitted trust claims, that they told the company one thing, I've only been exposed to your product or maybe a couple, but at the same time, they were going to other courts going to trust and saying, I've been exposed to 15 other products or 20. And that was enough for him to say, I don't accept any estimation based on settlements because I don't need to see any

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1 more. If it happened in 15 out of 15, that's enough for me.

So that's a long way of saying, Your Honor, that, again, the opposition, I guess, is not surprising based on what we've seen in other cases, but the PIQ, that's very basic discovery about the merits of the claims and trust discovery is $6\parallel$ very key with respect to alternative exposures. And remember that the trust discovery is pursued against trusts who all have electronic databases. It takes them a push of the button to spit that data out to provide it. There's no burden. companies typically offer to pay the costs. That should not be a problem.

Mr. Satterley just misspoke on one point I'll comment on. He criticized us for proposing that the medical science hearings would be one day. I mean, our proposal was actually four days for ovarian, three days from mesothelioma, and obviously, that's a proposal we're making. We think, based on what we know and our experience in the tort system, that would be sufficient. But we're not saying that it's four and three and that's it, we're not willing to talk about that.

I thought you asked an interesting question of Mr. Molton about the value of the insurance and what you would do with that at confirmation. And his answer, I thought, which I think was the right answer was, well, you're going to have to do an aggregate liability determination at least to show that the liability exceeds one to two billion or three billion.

1 think he said three and a half billion as a hypothetical.

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And that's the point. There has to be an aggregate liability. There's no way to shortchange it. And he was very dismissive of it in the sense he says, oh, well, it'll be easy to show it's over three and a half billion. That's no problem Well, based on what? And following what discovery? 7 And based on what process are we going to determine that? Is he just going to come into Court and have someone say, well, it's obviously at least 10 billion? Well, fine, you can do that, but we have a right, I believe, to our discovery and our right to fully challenge any expert who takes that position.

The other thing, Your Honor, is we heard multiple 13 lawyers stand up here and say that this is all about delay. Delay, delay, delay. I think in the slide, Mr. Molton had at least three or four times, maybe in the same sentence. And I would just ask Your Honor who's been sitting through these hearings, who has been getting reports of some kind about the mediation, whether you believe there's any evidence that we have been delaying things. I would submit that the record clearly establishes exactly the opposite. And so it's one thing for Mr. Molton to stand up here and make those assertions. I didn't hear any evidence to back that up and I submit there is no evidence.

These companies want this case to move fast. We're 25 \parallel not interested in delay. We wish the mediation was over.

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1 wish it had succeeded by now. It hasn't happened for reasons $2 \parallel$ that are bothersome to us, but it is what it is. But we're trying to come up with other ways to focus the parties in the right way and to put them in a position to settle this sooner rather than later.

So I guess in the end, Your Honor, I would just say 7 this. All I hear and all I've heard from these counsel, one by one, is that we have a veto right, we can do what we want. make the demand. We decide. It's irrelevant what the debtor thinks. It's irrelevant what J&J thinks. And, frankly, they're trying to put you, I believe, in a position where it's very difficult for you to determine whether what they decide 13 \parallel for themselves works for them is actually fair and appropriate.

We're in a court process to try to fairly resolve this liability. And, you know, we believe that we have rights that we're entitled to to protect our interests in that respect. And I would just ask Your Honor to take those comments for what they are. I've heard them in every single case. We will never agree. We will never accept anything less than what we demand. Anything we say goes. Anything we say will be accepted by the claimants.

Well, my answer to that is we have a court process. This Court is here to find the truth and to do justice and that's what we're asking this Court to do.

THE COURT: Thank you, Mr. Gordon.